REMARKS

Reconsideration of the pending claims is respectfully requested in view of the foregoing amendments and the following remarks.

Amendments

Claims 55, 56, 59-61, 63, 65, 66, 73, 75, 76, 83, 85, 86, 93, 95 and 96 are amended to address non-substantive matters, with claims 64, 74, 84, and 94 being amended address the antecedent basis rejections, and claims 109 and 110 being new.

As these amendments are fully supported by the application as filed, no new matter has been introduced in to the application by way of these amendments.

Summary of the Office Action

Claims 55-110 are under examination.

Claims 55-63, 65-73, 75-83, 85-93, 95 and 96 are allowed.

Claims 97 through 108 are rejected under 35 U.S.C. § 112, first paragraph as allegedly being nonenabling.

Claims 64, 74, 84, and 94 are rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite because of an alleged insufficient antecedent basis for limitations recited by those claims.

Discussion of the Enablement Rejection

The Office Action rejects claims 99-108, directed to the use of the claimed compounds to treat cancer, under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. Specifically, Office Action contends that there is no teaching or data proving that the instant compounds are topoisomerase I inhibitors. In addition, the Office Action maintains its allegation that because only one cancer cell line (a breast cancer cell line) was used to show the anti-cancer activity of the claimed compounds, the application does not enable the claimed compounds use against "every type of known cancer." Applicants respectfully traverse.

The application explicitly teaches that, on the basis of their structures, the claimed compounds are topoisomerase I inhibitors, *e.g.*, in paragraph [0002] the specification states that "[t]he present invention relates the derivatives of camptothecin" and in paragraph [0004]

the specification states that "[c]amptothecin compounds inhibit the enzyme DNA topoisomerase I which is known to relax supercoiled DNA."

Moreover, in paragraph [0030] the specification states:

> The di-ester compounds of the present invention are active in inhibiting topoisomerase I and yet are non-toxic over a wide active dose range number... the present invention allows one to administer a much larger dose of camptothecin compound as the prodrug than as the corresponding parent camptothecin compound.

The Office Action fails to set forth any reasoning as to why the Applicants' assertion that the claimed compounds are topoisomerase I inhibitors is not credible.

At the time of the application's effective filing date, being camptothecins, the claimed compounds were members of a well established class of anticancer drugs whose members were known to have activity against a wide range of cancer types. *See, e.g.,* Garcia-Carbonero: Current Perspectives on the Clinical Experience, Pharmacology, and Continued Development of the Camptothecins, *Clinical Cancer Research 8,* 641–661, March 2002 (attached in IDS). In view of what was known about the camptothecins as a group, the specification's presentation of data from a breast cancer cell line confirms Applicants' assertions that the compounds have anticancer activity. Applicants further submit that, since the claimed compounds are campothecins, the results with the breast cancer cell line are reasonably correlated to generalized anticancer activity. *See,* MPEP § 2107.03.

Accordingly, undue experimentation would not be required to practice the invention described in claims 99-108. Although claims 99-108 are directed to the full range of cancers, those of ordinary skill upon reading the present application as filed would have expected the claimed compounds—which applicants discovered were campothecin topoisomerase I inhibitors—to have activity against a wide range of cancers. Thus, one skilled in the art, based on the disclosure provided by the Applicants in view of the knowledge processed by one skilled in the art (e.g., via teachings provided by the prior art), would be able to develop the claimed compounds (topoisomerase I inhibitors/anti-cancer compounds) into a wide spectrum anticancer drug without undue experimentation. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Withdrawal of the Section 112, first paragraph, rejection is again respectfully requested.

New claims 109 and 110 are were limited to treating of breast cancer, thus are in condition for allowance.

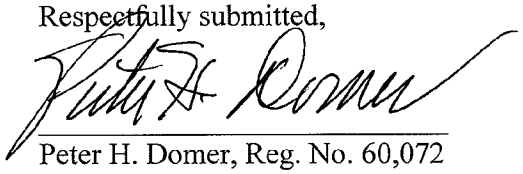
Discussion of the Indefiniteness Rejection

Claims 64, 74, 84, and 94 are rejected as allegedly being indefinite under 35 U.S.C. §112, second paragraph, because of an alleged insufficient antecedent basis for limitations recited in those claims. The allegedly indefinite limitation has been removed from each of these claims by amendment herein. Accordingly, Applicants submit that the indefiniteness rejections of claims 64, 74, 84, and 94 are moot.

Conclusion

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



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